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Initiation of home mechanical ventilation at home: A randomised controlled trial of efficacy, feasibility and costs



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Chronic ventilatory support;
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Telemonitoring

Summary

Introduction: Home mechanical ventilation (HMV) in the Netherlands is normally initiated in hospital, but this is expensive and often a burden for the patient. In this randomised controlled study we investigated whether initiation of HMV at home in patients with chronic respiratory failure is non-inferior to an in hospital based setting.

Methods: Seventy-seven patients were included, of which 38 patients started HMV at home. All patients were diagnosed with chronic respiratory failure due to a neuromuscular or thoracic cage disease. Primary outcome was the arterial carbon dioxide ($PaCO_2$) while quality of life and costs were secondary outcomes. Telemonitoring was used in the home group to provide therapeutic information, for example; transcutaneous carbon dioxide, oxygen saturation and ventilator information, to the caregivers. Follow-up was six months.

Results: $PaCO_2$ improved by 0.72 (SE \pm 0.16) kPa in the hospital group and by 0.91 (\pm 0.20) in the home group, both improvements being significant and the latter clearly not inferior.

There were also significant improvements in quality of life in both groups, again not being inferior with home treatment.

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Conclusion: This study is the first to show that initiation of HMV at home in a selective group of patients with chronic respiratory failure is as effective for gas exchange and quality of life as hospital initiation. In addition we found that it is safe, technically feasible and that more than € 3000 per patient can be saved compared to our standard care.

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Introduction

Home mechanical ventilation (HMV) in the Netherlands routinely starts in a clinical setting as recommended in the national guideline and typically requires several days, up to a week of hospitalisation [1]. Nocturnal arterial blood gas analysis while on HMV complete the initiation period and are performed at the intensive care. It is intuitive that the costs of starting HMV in a hospital setting are substantial higher than at home which is the topic of our study. In addition being admitted to a hospital for patients is not only an emotional burden, it also increases the risk of developing a nosocomial infection [2]. Patients on HMV are mostly severely disabled and it is often, perhaps paradoxically, challenging to provide the same high level of individually tailored care in hospital as compared to home. These are all very important reasons to investigate whether the initiation of HMV cannot be carried out in the home setting.

A problem of the initiation of HMV at home so far has been the lack of professional supervision in the home environment and night time observation during sleep. A probable solution for this problem is the use of telemonitoring to transmit digital data and provide clinical health care outside the hospital [3,4]. The data in patients with HMV comprises of ventilator settings and physiological data, for example carbon dioxide and oxygen saturation levels. It has been shown that telemonitoring can be cost-effective and in certain settings is able to transfer the burden of care from health-care professionals to family and home-care personnel [5]. In the latter study patients with chronic obstructive pulmonary disease (COPD) on oxygen or HMV were monitored by tele-assistance which reduced both hospitalisations and urgent calls compared to the control group that received standard care.

As we do not know if the initiation of HMV at home is effective, technically feasible and cost-effective we set up a randomised controlled trial.

Our hypothesis was that initiation of HMV at home, by using telemonitoring, in a selective group of patients with chronic respiratory failure due to neuromuscular disease (NMD) or thoracic cage disorder is not inferior compared to initiation in a hospital. The primary outcome measure was the arterial carbon dioxide (PaCO_2) while quality of life and costs were secondary outcome measurements.

Methods

Subjects

The study design was single-centre, prospective, randomised and controlled. Patients diagnosed with chronic

respiratory failure due to a NMD or thoracic cage disorder being referred to our outpatient clinic were screened for participation in this study. Chronic respiratory failure was defined as daytime $\text{PaCO}_2 > 6.0$ kPa (> 45 mmHg) [6,7] with complaints of respiratory failure (pulmonary infections, headache, daytime sleepiness, concentration problems) as stated in our national guideline. [1] Patients with orthopnea due to diaphragm paralysis and daytime normocapnia were also included. Patients younger than 18 years, those who needed invasive ventilation and the ones that lived in a nursing home were excluded. We excluded patients with strictly COPD as HMV is not a standard therapy in the Netherlands in those patients. Patients not naïve to a mask, for example failure after CPAP therapy and patients with an acute episode of respiratory failure were also excluded. The study was approved by the Medical Ethics Committee of the University of Groningen, University Medical Center of Groningen and written informed consent was obtained from all patients. The trial was registered with the Netherlands Trial Registry (NTR number 1476).

Randomisation and intervention

Patients started HMV at home or in the hospital in random order. Stratification was done for patients with Amyotrophic Lateral Sclerosis (ALS) to prevent a possible imbalance between the two groups. Randomisation was done by an independent statistician using a stratified block randomisation with a block size of 6.

Measurements

Daytime arterial blood gasses were taken from the radial artery, in sitting position and without oxygen supplementation or HMV at baseline and 6 months after the initiation of HMV at the outpatient clinic.

Patients completed the following questionnaires: Severe Respiratory Insufficiency (SRI) [8], Mageri Respiratory Failure (MRF-28) [9], Hospital Anxiety and Depression Scale (HADS) [10] and the Short-Form Health Survey (SF-36) [11]. The SRI contains seven domains; respiratory complaints, physical functioning, attendant symptoms and sleep, social relationships, anxiety, psychological well-being and social functioning. The MRF contains three domains; daily activity, cognitive function and invalidity. The HADS contains the anxiety and depression domain. The SF-36 contains eight domains; physical functioning; role physical; bodily pain; general health; vitality; social functioning; role emotional and mental health.

Forced vital capacity was measured by spirometry (Masterscreen® Viasys, Bodystat Ltd, Isle of Man, UK.).

Carbon dioxide and oxygen saturation were assessed through the skin of the earlobe, by Tosca® (Linde Medical Sensors AG, Basel, Switzerland) [12].

A standard procedure describing the technical setup of HMV was used both at home and in the hospital. All patients started with the Elisée 150® ventilator (ResMed Paris, Fr.). The choice of the interface could be a nasal, full-face, mouth or total-face mask. The ventilator in the pressure mode was set up at the start with an inspiratory pressure of 10 cm H₂O; a positive end expiratory pressure (PEEP) of 4 cm H₂O; a target volume of 8–10 ml/kg and a ventilatory rate close to the patients breathing frequency. The set up in the volume mode started at a volume of 8–10 ml/kg; a PEEP of 4 cm H₂O and a ventilatory rate close to the patients breathing frequency. The standard procedure described which actions should be taken to change the ventilator settings during the initiation of HMV. For example, if the patient needed more air, the inspiratory pressure was increased and if the patient snored during the PEEP was increased. During the initiation of HMV adjustments to the ventilator and or interface were done to improve the blood gasses and the patients comfort resulting in a good night sleep.

Initiation of home mechanical ventilation in the hospital

Standard care during the initiation of HMV in our hospital entails admission on a regular respiratory ward with specifically trained personnel. The first day of admission the patient started HMV with the intention to get used to the interface and to adjust to the ventilator settings. Patients were instructed to use the ventilator as long as possible during the first night. They were allowed to stop the HMV during the night and if applicable start again early in the morning for another session. Every day the necessary actions including, adjusting ventilator settings or interface were performed. The patient had to sleep at least 6 h with the ventilator, before he was transferred to the intensive care unit (ICU) to assess arterial blood gasses, through a radial catheter, during the night while using the HMV. The latter being the standard routine in the Netherlands. If normalisation of carbon dioxide and oxygen saturation levels while on the ventilator were reached, the patient was discharged. The ventilator was installed at home by a nurse of the department of HMV. After two months the patient was admitted again to the ICU for nocturnal arterial blood gas assessment while on HMV. The patient had to bring their own home ventilator to the hospital.

Follow-up was six months after starting HMV at the outpatient clinic to assess an arterial blood gas analysis and lung function.

Initiation of home mechanical ventilation at home

Initiation of HMV at home started during the first visit at the patient's home by the nurse practitioner (NP). The ventilator, humidifier and transcutaneous monitor were installed in the patient's bedroom (Fig. 1). This installation also included the laptop, mobile connection and the software program that was used to send digital data of the devices to



Figure 1 Setup of the telemonitoring equipment at home. Ventilator Elisée 150®, humidifier Fisher and Paykel HC 150®, transcutaneous monitor Tosca®, laptop with mobile connection.

the hospital. The first time the patient was ventilated the NP was present. After instruction was given to the patient and if necessary to the caregivers they practiced the HMV themselves at daytime. If in the first night, when trying to sleep with the HMV, the patient woke up and could not continue because of discomfort they were allowed to stop. The following days and nights they tried to extend the number of hours on HMV. Patients were instructed to call the department of HMV 24/7 if problems occurred. If sputum mobilisation was a problem patients were instructed to use air stacking and one ventilator mode was adjusted for mouthpiece ventilation. Every day the ventilator information (e.g. volume, frequency, pressure levels, hours ventilator was used) was sent to the hospital and evaluated by the NP. The NP informed the patient about the results over the telephone and if necessary the ventilator settings were adjusted by the patient or the care giver. Changing the ventilator settings while on the phone with the NP is part of the instruction at the start of HMV. The transcutaneous monitor was attached the moment the patient could sleep for six hours while being on HMV. The next day the measurements of the transcutaneous monitor and the ventilator were evaluated, by using telemonitoring. When the results showed a normalisation of the carbon dioxide and oxygen saturation, the initiation period was ended during a house call by the NP. The transcutaneous monitor and the telemonitoring equipment were returned to the hospital. Two months after the initiation of HMV, transcutaneous monitoring at home was performed again.

Follow-up was six months after starting HMV at the outpatient clinic to assess an arterial blood gas analysis and lung function.

Telemonitoring

Every morning during the initiation period of HMV at home, the data of the ventilator and if applicable of the transcutaneous monitor was sent to the hospital. The data comprised of ventilator settings, respiratory rate and

carbon dioxide and oxygen saturation levels. The NP received the anonymised digital data by email and phoned with the patient to evaluate the results. A laptop was used to transfer the information collected by the ventilator and transcutaneous monitor to the hospital. A software program especially developed for this study started the data collection of the ventilator and transcutaneous monitor automatically.

Cost analysis

Units of health care consumption that were registered included admission days to the general ward and ICU, time spent by the nurse practitioner (including house calls) and travelling expenses. Volumes of health care consumption were multiplied with their cost prices according to the Dutch guideline for cost studies [13]. The 2012 price level was used. Costs are displayed in Euro's (€). The time horizon of the cost study was equal to that of the clinical study and was 6 months. Mean total costs per patient were calculated for both interventions separately. Confidence intervals (95%CI's) were computed based on bootstrap re-sampling with 5000 replications of the trial dataset.

Statistical analysis

The primary outcome analysis was PaCO_2 which was based on intention-to-treat (ITT) analysis. The power analysis was based on a non-inferiority test of the difference of two means. With an alpha of 0.05, a beta of 0.2, a standard deviation off 0.71 and a maximum difference in PaCO_2 of 0.5 kPa, it was necessary to have two groups of 26 patients. A paired-sample *T*-test was performed to determine the difference within groups and an independent-sample *T*-test for the difference (Δ) between groups. The level of statistical significance was set at $p < 0.05$. Statistical analyses were performed using IBM SPSS Statistics 20 (IBM, New York, USA).

Results

380 patients started non-invasive HMV in the University Medical Center of Groningen (UMCG) during the inclusion period which lasted from October 2008 till October 2012 (Fig. 2). Of the 84 patients that were eligible, 77 were randomised (Table 1). Eight in each group withdrew during follow-up. *Additional information in the Supplementary*

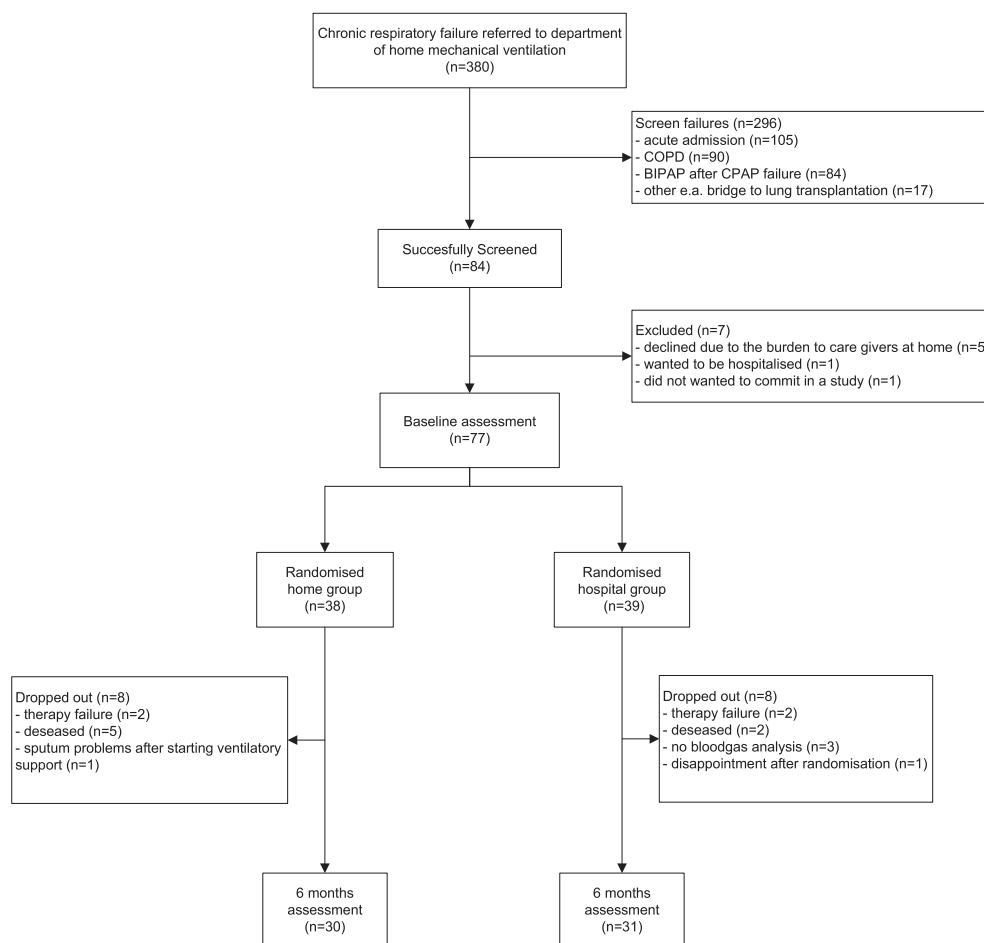


Figure 2 Flow diagram. Home group: initiation of home mechanical ventilation at home. Hospital group: initiation of home mechanical ventilation in the hospital. COPD: chronic obstructive pulmonary disease. BIPAP: bi-level positive airway pressure. CPAP: continuous positive airway pressure.

Table 1 Baseline characteristics.

	Home group (n = 38)	Hospital group (n = 39)
Male	20	25
Age in years	59.9 ± 12.6	56.9 ± 13.9
Neuromuscular disease	33	35
Thoracic cage disorder	5	4
Body mass Index kg·m ²	27 ± 6.3	27 ± 6.8
Blood gas analysis room air		
Ph	7.40 ± 0.3	7.40 ± 0.3
PaCO ₂ kPa	6.6 ± 0.9	6.6 ± 1.1
PaO ₂ kPa	10.0 ± 1.7	9.5 ± 1.3
SaO ₂ %	95 ± 2.9	94 ± 2.7
HCO ₃ mmol/l	30.2 ± 3.8	30.4 ± 3.8
VC % predicted	50.3 ± 20.9	51.6 ± 18.1
FEV ₁ /VC	79.3 ± 12.2	81.2 ± 15.7
Pack years	14.3 ± 11.2	29.5 ± 17.8
Current smokers	2	3
Wheelchair-bound	16	12

Data are presented as n or mean ± SD.

kPa: kilopascal. Ph: acidity level. PaCO₂: partial pressure of arterial carbon dioxide. PaO₂: partial pressure of arterial oxygen. SaO₂: arterial oxygen saturation. HCO₃: bicarbonate. VC: vital capacity. FEV₁: forced expiratory volume in one second.

files Table 1. The largest group in this study was diagnosed with ALS (4 with bulbar involvement); 10 patients in the hospital group had diaphragm paralysis and 4 in the home group. Two patients crossed from intervention, one in the hospital group and the other in the home group. They remained in the initial group for all ITT analysis. Both analysis per protocol and ITT did not result in different outcomes. We also evaluated the variety in diagnoses and did not find a significant difference between both groups.

One patient with limb girdle dystrophy in the home group and 1 patient with ALS in the hospital group used HMV when their blood gasses were assessed during 6 months follow-up due to the progression of their illness.

In the home group 5 patients died versus 2 in the hospital group. In no case was this due to technical problems in the home settings. Patients died varying from one week up to almost 6 months after starting HMV, all experiencing a non-acute progression of their disease (ALS).

Twenty-five patients in the home group and 28 patients in the hospital group were not able to perform physical activities regarding the maintenance of HMV. The care givers were instructed during the initiation of HMV at home while this was done after being discharged in the hospital group.

Blood gas analysis and ventilator settings

Daytime PaCO₂, the primary endpoint, improved by 0.72 (SE ± 0.16) kPa in the hospital group and by 0.91 (±0.20) in the home group being not significantly different between both groups (Table 2). Nocturnal transcutaneous registration showed an improvement in both groups, both after initiation and after two months (Table 3).

Both groups started with the same ventilator settings and only minor adjustments were needed during the follow-up of six months (Fig. 3). Three patients were ventilated in the volume mode and the other 74 in the pressure controlled mode. In the home group a mean of 11 (±1.86) days was needed to initiate HMV and in the hospital group 8 (±0.54) days. Follow-up after 6 months showed that patients at home slept a mean of 10.0 (±0.83) hours with HMV and the hospital group 8.5 (±0.67) hours.

Health related quality of life

The hospital and home group improved significantly on two of seven SRI subscales. The improvements in SRI score from baseline to six months follow-up were not inferior (or significantly better) in the home group compared to the hospital group.

The MRF-28 showed a significant improvement in the hospital group on the total score but not in the home group, however not being significantly different between both groups. The other MRF-28 domain scores were both within and between groups not significantly different. The HADS showed no significant changes both within and between groups. The SF-36 showed a significant improvement in the domain vitality in both groups. The other SF-36 domains showed no significant changes between groups (Table 4).

Costs

Due to the travel time in the home group the total invested time by NP per patient was 91 min longer compared to the hospital group. In contrast the contact time per patient in the hospital group was higher (Fig. 4). The NP visited the patient the first day and if necessary the following days. This was not specified in the standard procedure and resulted in a mean of 3 visited during the initiation period of HMV.

Total mean costs per patient amounted to € 726 per patient in the home group and to € 3913 in the hospital group (difference – € 3187; 95% CI –€3643 to –€ 2694). Mean costs in the hospital group amounted to € 3618 for admission to the ICU and the ward, €198 for contact with the NP and € 97 for travelling expenses. Mean costs in the home group included € 192 of travelling expenses, € 266 of house calls and consult by telephone by the nurse practitioner, and € 268 for hospital admissions. As the other costs; masks, ventilator, disposables supply and transcutaneous measurement were similar in both groups this was not accounted for.

Telemonitoring

Since the procedure of initiation of HMV at a distance, i.e. at home, is new and the software program for telemonitoring was specifically developed for this study, patients were instructed to contact the 24/7 call service of the HMV department if necessary. The use of telemonitoring did not result in problems or calls during the night. Adjusting ventilator settings, while interacting with the patient or caregivers, went well after good instructions during the initiation process.

Table 2 Changes in daytime arterial blood gasses and lung function pre home mechanical ventilation to 6 months after the start.

	Home group (n = 30)			Hospital group (n = 31)		Between groups	
	Baseline	Follow-up	P-Value ^a	Baseline	Follow-up	P-Value ^a	P-value ^b
Ph	7.40 ± 0.3	7.40 ± 0.3	0.261	7.40 ± 0.3	7.40 ± 0.3	0.913	0.423
PaCO ₂ (kPa)	6.6 ± 0.9	5.7 ± 0.8	0.000	6.6 ± 1.1	5.9 ± 0.8	0.000	0.631
PaO ₂ (kPa)	10.0 ± 1.7	11.3 ± 2.2	0.002	9.5 ± 1.3	10.3 ± 1.7	0.015	0.579
SaO ₂ %	95 ± 2.9	96 ± 1.9	0.020	94 ± 2.7	95 ± 3.6	0.348	0.598
HCO ₃ (mmol/l)	30.2 ± 3.8	26.6 ± 3.1	0.000	30.4 ± 3.8	26.9 ± 2.5	0.000	0.996
aBE	4.9 ± 2.6	2.6 ± 1.7	0.000	4.8 ± 2.8	2.2 ± 1.8	0.000	0.283
FVC (% pred)	51.6 ± 22.8	53.4 ± 21.8	0.528	52.4 ± 18.5	49.8 ± 19.0	0.301	0.428

Data are presented as n or mean ± SD.

kPa: kilopascal. Ph: acidity level. PaCO₂: partial pressure of arterial carbon dioxide. PaO₂: partial pressure of arterial oxygen. SaO₂: arterial oxygen saturation. HCO₃: bicarbonate. VC: vital capacity. Follow-up: six months after the initiation of home mechanical ventilation.

Bold: *p* < 0.05 significant change.

^a P-value refers to paired *t* test analysis from starting ventilatory support to six months follow-up within each group.

^b P-value for difference in change Δ from baseline between groups.

Table 3 Changes in nocturnal transcutaneous carbon dioxide and oxygen saturation.

	Home group (n = 30)			Hospital group (n = 31)		
	Baseline	After initiating HMV	2 months follow-up	Baseline	After initiating HMV	2 months follow-up
tcpCO ₂ (kPa)	7.6 ± 1.0	6.5 ± 0.9	5.8 ± 0.7	7.4 ± 1.3	6.4 ± 0.8	5.7 ± 0.7
Maximal tcpCO ₂ (kPa)	8.7 ± 1.4	7.3 ± 0.9	6.7 ± 0.8	8.4 ± 1.8	7.3 ± 0.9	6.6 ± 0.2
Oxygen saturation (%)	91.3 ± 5.1	95.2 ± 1.8	96.2 ± 1.8	91.8 ± 4.9	95.7 ± 1.7	95.9 ± 1.7
Lowest oxygen saturation (%)	74.6 ± 15.2	86.6 ± 8.2	84.7 ± 12.8	74.4 ± 14.6	84.1 ± 9.2	85.7 ± 7.2

Data are presented mean ± SD.

tcpCO₂: transcutaneous carbon dioxide. kPa: kilo pascal.

Technical problems did occur initially in 11 out of the 38 patients who started HMV at home. In 3 patients the wireless connection was not successful because of insufficient mobile connection facilities as our part of the country is not very

densely populated. Another reason was that patients with ALS sometimes live in an iron surfaced mobile unit, with bedroom and washroom facilities on the ground floor. The iron surface disturbs the mobile connection. In these 11 cases the evaluation of the patients' condition was done on individual clinical parameters; sleeping time with HMV, sleep quality and improvement of quality of life during the day.

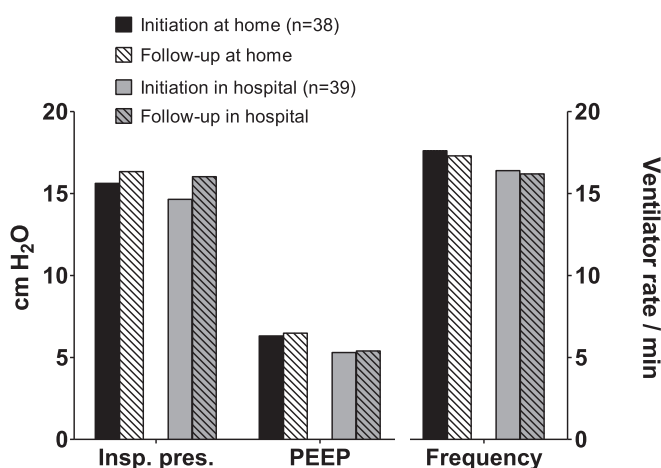


Figure 3 Ventilator settings from initiation to six months follow-up. Insp. pres: inspiratory pressure in cm H₂O above peep. PEEP: positive end expiratory pressure in cm H₂O. Frequency: ventilator frequency. Initiation: after the initiation of home mechanical ventilation. Follow-up: 6 months follow-up after starting home mechanical ventilation.

Discussion

This is the first study showing that initiation of home mechanical ventilation at home, in a selective group of patients with a stable respiratory problem, resulted in improvements in blood gasses and quality of life being not inferior to in hospital initiation. In addition it showed that the start of HMV at home, by using telemonitoring, was safe, feasible and cheaper.

Publications concerning the initiation of HMV outside the hospital by using telemonitoring are scarce. One study showed a reduction in health care utilization in patients with ALS after using home telemonitoring [14]. Initiation of HMV was done in the hospital and the follow-up was carried out at home by using telemonitoring. They used a fixed telephone line with limited speed of data transferral. In our study we started HMV at home and we used a mobile connection allowing us to move the equipment from one

Table 4 Changes in health related quality of life measurements pre home mechanical ventilation to 6 months after the start.

	Home group (n = 30)			Hospital group (n = 35)		Between groups	
	Baseline	Follow-up	P-value ^a	Baseline	Follow-up	P-value ^a	P-value ^b
SRI							
RC	47.6 ± 19.5	55.5 ± 17.3	0.023	48.6 ± 18.5	51.9 ± 17.6	0.114	0.462
PF	28.8 ± 21.4	31.9 ± 21.5	0.994	36.6 ± 20.5	32.9 ± 20.5	0.452	0.585
AS	55.1 ± 18.6	69.6 ± 18.0	0.000	48.5 ± 19.1	60.9 ± 16.7	0.000	0.904
SR	68.5 ± 12.3	69.5 ± 12.7	0.723	71.2 ± 12.8	66.9 ± 11.8	0.204	0.247
AX	55.0 ± 21.1	57.8 ± 24.2	0.474	54.7 ± 16.8	60.9 ± 16.7	0.159	0.628
WB	57.1 ± 19.8	57.3 ± 24.0	1.000	60.3 ± 15.7	59.7 ± 18.3	0.946	0.963
SF	52.7 ± 19.1	51.9 ± 22.3	0.298	57.2 ± 17.5	55.1 ± 18.5	0.733	0.603
SS	52.1 ± 14.4	56.2 ± 16.4	0.153	53.9 ± 12.3	55.4 ± 12.0	0.248	0.762
MRF-28							
Daily activities	58.1 ± 27.9	59.7 ± 27.6	0.741	60.3 ± 29.0	53.2 ± 28.1	0.182	0.706
Cognition	35.0 ± 32.6	29.4 ± 33.5	0.372	37.1 ± 35.4	30.0 ± 34.7	0.143	0.836
Invalidity	53.3 ± 38.5	61.3 ± 37.1	0.241	57.1 ± 34.7	57.1 ± 34.7	1.000	0.333
Total score	52.1 ± 21.1	49.2 ± 23.1	0.466	58.2 ± 19.7	45.2 ± 20.9	0.000	0.038
HADS							
Depression	6.6 ± 4.2	6.0 ± 4.5	0.319	7.1 ± 3.5	6.4 ± 4.2	0.139	0.985
Anxiety	6.4 ± 4.7	6.1 ± 4.9	0.193	6.8 ± 3.8	6.1 ± 3.4	0.195	0.589
Total score	13.0 ± 8.0	12.1 ± 8.7	0.660	13.9 ± 6.8	12.5 ± 7.1	0.175	0.760
SF-36							
PF	13.2 ± 18.5	15.6 ± 19.1	0.832	17.1 ± 22.1	18.8 ± 23.6	0.784	0.983
RP	15.7 ± 33.6	25.0 ± 35.9	0.565	13.1 ± 24.4	25.7 ± 35.0	0.013	0.337
BP	66.8 ± 30.7	66.1 ± 29.6	0.853	64.2 ± 29.2	60.5 ± 24.5	0.612	0.863
GH	30.7 ± 24.8	35.2 ± 27.2	0.805	30.2 ± 17.3	36.0 ± 19.6	0.058	0.205
VT	39.0 ± 21.4	52.1 ± 22.6	0.004	36.5 ± 18.9	45.2 ± 18.9	0.004	0.967
SF	52.6 ± 32.9	58.7 ± 32.8	0.881	55.0 ± 21.7	60.3 ± 27.3	0.338	0.602
RE	54.3 ± 52.8	57.4 ± 47.0	0.508	48.2 ± 46.3	57.1 ± 45.4	0.209	0.864
MH	66.3 ± 21.8	72.2 ± 22.0	0.040	64.7 ± 17.5	69.7 ± 17.0	0.055	0.993

Data are presented as n or mean ± SD.

SRI: Severe Respiratory Insufficiency (0 = worst possible health 100 = best possible health) respiratory complaints (RC), physical functioning (PF), attendant symptoms and sleep (AS), social relationship (SR), anxiety (AX), psychological well-being (WB), social functioning (SF), summary score (SS).

MRF-28: Mageri Respiratory Failure (0 = worst possible health 100 = best possible health).

HADS: Hospital Anxiety Depression Scale (total score: 0 = best possible health 42 is worst possible health; separate score 0–21).

SF-36: Short-Form Health Status Survey (0 = worst possible health 100 = best possible health) PF = physical functioning, RP = role physical; BP = bodily pain; GH = general health; VT = vitality; SF = social functioning; RE = role emotional; MH = mental health. Bold: $p < 0.05$ significant change.

^a P-value refers to paired *t* test analysis from starting ventilatory support to six months follow-up within each group.

^b P-value for difference in change Δ from baseline between groups.

patient to the other without technical workout delays. Another study showed that telemonitoring can be more effective in patients who are more compliant to the therapy [15]. The installation of the telemonitoring system at the patient's home in our study was self-supporting meaning that the data transfer was not dependent on the technical skills or actions to be taken by the patient or compliance to therapy. A third study compared the initiation of HMV between inpatient and outpatient titration but did not use telemonitoring [16]. The improvement of blood gasses was equivalent between the two groups which is comparable to our study. However patients included in our study had a mean PaCO_2 of 6.6 kPa while in the study of Chatwin patients had near normal daytime PaCO_2 .

Our data provides a good example in the field of implementation of telemonitoring while not all studies have been successful so far. We believe that the results of this study contribute to the fact that the use of modern

technologies in patients with a chronic disease can lower the burden to the health care system.

Earlier studies showed an improvement in blood gasses after the initiation of HMV [17,18]. We found a comparable improvement in blood gasses in both groups indicating that the initiation of HMV can be performed effectively at home in a selective group of patients with chronic respiratory failure due to a neuromuscular disease of thoracic cage disorder. Nevertheless it is obvious that a thorough scan of the home environment must be performed before starting HMV.

This study also showed that it is possible to initiate HMV at home in patients with an age varying from 19 to 80 years of age. The youngest and the oldest started HMV at home and we did not notice any age related problems. In some cases the absence of a partner or family member resulted in recruiting home care professionals to support the patient during the first steps of HMV at home. In the home group

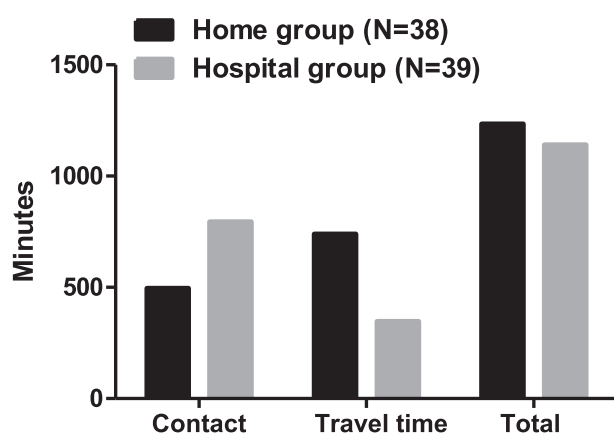


Figure 4 Time spent during initiation of home mechanical ventilation and 6 months follow-up. Contact: direct contact between the patient and the care giver of the department of home mechanical ventilation from initiation to 6 months follow-up. Travel time: driving time between hospital and patient during house calls. Total: is all time added up.

patients started HMV one week after being included and in the hospital group this was 3 weeks. This delay in the hospital group was due to limited number of beds in the hospital.

As in our center the initiation of HMV is done in a hospital based setting and therefore expensive, the present study was performed to search for an alternative. The medical ethics committee agreed to initiate HMV outside the hospital directly instead of starting in an outpatient clinic or on a ward without ICU admission first. This was done to save time and to facilitate patients to stay at home. Initiating HMV at home was not only effective and safe, it was also cost-effective. This study showed a mean reduction of € 3187 per patient when HMV started at home. Mobile data communication costs were negligible and variable and therefore not included in the total costs analysis. Since we initiate HMV in the Netherlands in approximately 600 patients per year [19], full implementation nationwide would save over € 1.8 million annually. Despite this enormous cost reduction we should stress the point that the inpatient initiation is very expensive being primarily due to the ICU admission. When the initiation is done on a non-ICU ward the benefit in costs would be lower compared to our situation.

Despite these positive results this study has some limitations.

Above all, there was a large group of patients with chronic respiratory failure that did not participate in this study for various reasons (Fig. 1). We excluded all patients with COPD as providing HMV to this group is still not current practice in our country. A recent meta-analysis showed that HMV in stable patients with COPD did not improve gas-exchange, lung function or QOL [20]. In this study only 2 patients with OHS were enrolled which is remarkable considering the growth of patients with OHS that start HMV [21]. The reason was that 27 patients with OHS had to start with HMV in hospital immediately due to an acute respiratory failure.

Secondly, the effect of HMV with regard to quality of life (QOL) in our total group compared to previous studies

seems to be less positive. Probably this is due to the large number of ALS patients included in our study, which was over the 35%. Although Bourke concluded that HMV in ALS does improve QOL, this was based on the increased duration of time (compared to control group) that the QOL was maintained above 75% of their baseline value [22]. As we assessed absolute values of QOL it is difficult to compare both studies. If we excluded the ALS group we did find a significant improvement in several domains being comparable with the previous studies.

Another limitation of this study was that the initiation of HMV was done by just one NP in the home group. As we cannot conclude, based on this single study, that it can be duplicated in all other situations, we recommend an additional study were the implementation of this concept on a broader scale i.e. other regions, settings and with more people involved should be examined. Improvements in the technical and digital opportunities, during the last couple of years, will facilitate the development of future tele-monitoring studies. Especially the use of polysomnography and microchip cards with detailed ventilator information, can be of great importance in future studies to better evaluate the patient-ventilator interaction.

Conclusion

In summary we showed that initiation of HMV at home in a selective group of patients with chronic respiratory failure due to neuromuscular disease or thoracic cage disorder is effective for gas exchange and quality of life and is not less effective than initiation in the hospital. In addition we found that it is safe and that more than € 3000 per patient can be saved. From a patients' perspective it is an ideal treatment as they do not have to be admitted to the hospital and their highly individualised care can be maintained during the initiation of HMV.

Statement of interest

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.rmed.2014.07.008>.

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